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Application No.	Ref.	Date
00 965 015.1 - 2112	AHB/FP5999917	19.03.2009
Applicant: Ocularis Pharma, Inc.		

Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC. One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).

Nyeki, Agnes
Primary Examiner
For the Examining Division

Enclosure(s): 2 page/s reasons (Form 2906)

Registered Letter
EPO Form 2001 12.07CSX

The examination is being carried out on the **following application documents:**

Description, Pages

1-17 as originally filed

Claims, Numbers

1-14 filed with entry into the regional phase before the EPO

Amendments / Additional Subject-Matter (Article 123(2) EPC)

1. The amended Claims 1-11 filed with entry into the European phase introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 123(2) EPC. The originally filed independent Claims 1 and 4 refer to the administration of an alpha 1 antagonist "to an eye". However, this feature is missing from new Claims 1 and 4 resulting in a generalization.

2. New Claims 12-14 meet the requirements of Article 123(2) EPC.

Prior art documents

3. Reference is made to the following documents:

   D1: ALSTER YAIR ET AL: "Dapiprazole for patients with night haloes after excimer keratectomy" GRAEFE'S ARCHIVE FOR CLINICAL AND EXPERIMENTAL OPHTHALMOLOGY, vol. 234, no. SUPPL. 1, 1996, pages S139-S141

   D2: MAGOR A ET AL: "Adrenergic pupillary responses in the spontaneous hypertensive rat" BIOGENIC AMINES, VNU SCIENCE PRESS, UTRECHT, NL, vol. 6, no. 2, 1 January 1989 (1989-01-01), pages 129-133

   D3: US-A-4 443 441 (GALIN MILES A [US]) 17 April 1984 (1984-04-17)

   D4: FAWCETT J P ET AL: "ANTIDEPRESSANT TREATMENT AND CHEMICAL SYMPATHECTOMY FAIL TO MODULATE ALPHA1-ADRENOCEPTOR SENSITIVITY IN MOUSE EYE" NEUROPHARMACOLOGY, PERGAMON PRESS, OXFORD, GB, vol. 32, no. 12, 1 January 1993 (1993-01-01), pages 1373-1379

   D5: US-A-5 288 759

Clarity (Article 84 EPC)

4. Independent Claims 1 and 4 appear to be drafted in a second medical use format and relate to the preparation of a therapeutic agent for "optimizing pupil diameter". It is considered however that this definition fails to clearly define the group of diseases for which protection is presently sought. Since second medical use claims are in principle based on a new medical use for a known substance or composition, they should clearly define the diseases, pathological conditions or group of patients to be treated.
It is not, therefore, presently possible to give a definitive assessment of the novelty or inventive step of Claims 1-11.

Novelty (Article 52(1), 54(1) and 54(2) EPC)

5. The present application does not meet the requirements of Article 52(1) EPC, because the subject-matter of Claims 12-14 is not new in the sense of Article 54(1) and 54(2) EPC.

6. D1 discloses an eye drop comprising dapiprazole, a miotic alpha-blocker drug.
D2 discloses the miotic effect of phentolamine given as an eye drop.
D3 claims the use of ophthalmic solutions containing an alpha-adrenergic blocking agent selected from the group including thymoxamine, phentolamine and phenoxybenzamine.
D4 discloses the topical use of alpha 1 antagonists, such as prazosin and phentolamine to produce miosis and completely block methoxamine-induced mydriasis.
D5 reports that the alpha-1 adrenergic antagonists dapiprazole and amsulosine are effective in reversing phenylephrine-induced mydriasis.
In view of D1-D5, the subject-matter of Claims 12-14 cannot be considered novel.

Concluding remarks

7. The Applicant is invited to overcome the raised objections by suitable amendments or explanations where possible. The attention of the Applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC).